



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Steinunn Baekkeskov *et al.*

Application No.: 08/838,486

Filed: April 7, 1997

For: IMPROVED METHODS FOR THE
DIAGNOSIS AND TREATMENT OF
DIABETES

Examiner: G. Ewoldt

Art Unit: 1644

SECOND DECLARATION OF
STEINUNN BAEKKESKOV UNDER 37
CFR §1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Steinunn Baekkeskov, state as follows:

1. I have previously submitted a declaration in these proceedings. My experience and qualifications are summarized in that declaration.
2. In the present declaration, I address two additional points raised in the final office action.
3. As discussed in my previous declaration and an accompanying Press Release, a phase II clinical trial is being conducted to test treatment of GAD on patients with a subtype of type II diabetes termed LADA (Latent Autoimmune Diabetes in Adults). A 6-month report on the trial provided evidence that administration of 20 micrograms GAD was safe and provided statistically significant evidence of efficacy over placebo ($p=0.0008$). Recently the 18-month data from the Phase II studies were released (Immunology of Diabetes Society's 7th Congress, March 29-31, 2004, Cambridge, England). The report showed that the positive effect on insulin production achieved six months after treatment still remains eighteen months after treatment and provided evidence that this effect is mediated by induction of regulatory T-cells (CD4+CD25+) (see enclosed press release of

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